# AGEN AS PROTECTION

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

## Note to Reader September 9, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

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available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. It is not meant to be a summary of all current information regarding the chemical. Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Yack Housenger, Acting Director Special Review and Reregistration

Division



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 9, 1998

#### MEMORANDUM

SUBJECT: Review of Ethoprop Incident Reports

DP Barcode D243371, Chemical #041101, Reregistration

Case #0106

FROM: Jerome Blondell, Ph.D., Health Statistician

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TO: Kathryn Boyle, Chemist

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#### **BACKGROUND**

The following data bases have been consulted for the poisoning incident data on the active ingredient Ethoprop (PC Code: 041101):

- 1) OPP Incident Data System (IDS) reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.
- 2) Poison Control Centers as the result of Data-Call-Ins issued in 1993, OPP received Poison Control Center data covering the years 1985 through 1992 for 28 organophosphate and carbamate chemicals.

Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.

- 3) California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.
- 4) National Pesticide Telecommunications Network (NPTN) NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

#### ETHOPROP REVIEW

#### I. Incident Data System

Please note that the following cases from the IDS do not have documentation confirming exposure or health effects unless otherwise noted.

#### Incident#690-1

Suicide was attempted by a chronic alcoholic, chronic smoker, and HIV+ man who ingested an unknown quantity of ethoprop (10% granular). The patient experienced respiratory arrest but recovered with rapid and intensive treatment.

#### Incident#749-1

A pesticide incident occurred in 1993, when a young child, who was hospitalized, ingested an unknown quantity of ethoprop. Specific symptoms were not mentioned. No further information on the disposition of the case was reported.

#### Incident#1184-1

A pesticide incident occurred in 1994, when a man mowed the tees at a golf course that was treated with ethoprop several hours earlier and experienced dizziness, nausea, headaches, and pinpoint pupils. No further information on the disposition of the case was reported.

#### Incident#1710-1

A pesticide incident occurred in 1994, when a twenty-two year old man sprayed fields without a mask with ethoprop and experienced vomiting several times, constricted pupils, and flushed skin. No further information on the disposition of the case was reported.

#### Incident#2721-1

A pesticide incident occurred in 1995, when a man, who was not wearing PPE, was changing screens and was exposed dermally and by inhalation. Specific symptoms were not mentioned. No further information on the disposition of the case was reported.

#### Incident#2721-2

A pesticide incident occurred in 1995, when a woman, who was not wearing PPE, was exposed by inhalation while cleaning up ethoprop bags. Specific symptoms were not mentioned. No further information on the disposition of the case was reported.

#### II. Poison Control Center Data

Ethoprop was one of 28 chemicals for which Poison Control Center (PCC) data were requested. The following text and statistics are taken from an analysis of these data; see December 5, 1994 memo from Jerome Blondell to Joshua First.

The 28 chemicals were ranked using three types of measures: (A) number and percent occupational and non-occupational adult exposures reported to PCCs requiring treatment, hospitalization, displaying symptoms or serious life-threatening effects; (B) California data for handlers and field workers comparing number of agricultural poisonings to reported applications; and (C) ratios of poisonings and hospitalization for PCC cases to estimated pounds reported in agriculture for pesticides used primarily in agriculture.

#### A. Occupational and Non-occupational Exposure

There were a total of 75 ethoprop cases in the PCC data base. Of these, 31 cases were occupational exposure; 26 (84%) involved exposure to ethoprop alone and 5 (16%) involved exposure to multiple chemicals, including ethoprop. There were a total of 38 adult non-occupational exposures; 32 (84%) involved this chemical alone and 6 (16%) were attributed to multiple chemicals. In this analysis, four measures of hazard were developed based on the Poison Control Center data, as listed below.

- 1. Percent of all accidental cases that were seen in or referred to a health care facility (HCF).
- 2. Percent of these cases (seen in or referred to HCF) that were admitted for medical care.
- 3. Percent of cases reporting symptoms based on just those cases where the medical outcome could be determined.
- 4. Percent of those cases that had a major medical outcome which could be defined as life-threatening or resulting in disability.

Exposure to ethoprop alone or in combination with other chemicals was evaluated for each of these categories, giving a total of 8 measures. A ranking of the 28 chemicals was done based on these measures with the lowest number being the most frequently implicated in adverse effects. Table 1 presents the analyses for occupational and non-occupational exposures.

Table 1: Measures of Risk From Occupational and Non-occupational Exposure to Ethoprop Using Poison Control Center Data from 1985-1992<sup>a</sup>

	Occupational Exposure	Non-occupational Exposure		
Percent Seen in HCF				
Single chemical exposure	80.8*6 (68.2)	50.0 (44.0)		
Multiple chemical exposure	80.6*6 (69.8)	55.3 (46.1)		
Percent Hospitalized				
Single chemical exposure	19.0 (12.2)	18.8*6 (9.9)		

 $<sup>^{1}</sup>$  Workers who were indirectly exposed (not handlers) were classified as non-occupational cases.

Multiple chemical exposure	16.0 (14.3)	14.3 (12.6)	
Percent with Symptoms			
Single chemical exposure	87.5 <sup>b</sup> (85.8)	83.3*5b (74.0)	
Multiple chemical exposure	90.0 <sup>b</sup> (85.8)	87.5*4b (75.2)	
Percent with Life-threatening Symptoms			
Single chemical exposure	0.0 <sup>b</sup> (0.0)	0.0 <sup>b</sup> (0.0)	
Multiple chemical exposure	0.0 <sup>b</sup> (0.5)	0.0 <sup>b</sup> (0.05)	

a Extracted from Tables 2, 3, 5 and 6 in December 5, 1994 memo from Jerome Blondell to Joshua First; number in parentheses is median score for that category.

Compared to other organophosphate and carbamate insecticides, ethoprop had above average evidence of effects, though for some measures (percent with symptoms or life-threatening symptoms) the number of cases was too few to provide reliable percentages (Table For both the occupational and nonoccupational categories, 1). cases were nearly twice as likely to hospitalization as did cases due to other cholinesterase inhibitors.

#### B. Ratios of poisoning - California Data

It is not possible to compare numbers of ethoprop poisoning in California to the number of applications because there have not been enough reports of systemic poisonings from 1982 through 1995. During this time period, there was only one occupational case reported for an applicator. However, there have been relatively limited use of ethoprop in California. From 1990 through 1994, total commercial applications ranged from 188 to 340.

#### C. Exposure in Children

A separate analysis of the number of exposures in children five years of age and under from 1985-1992 was conducted. For ethoprop, there were 6 incidents involved exposure to ethoprop alone. This number of cases was too few to warrant comparisons with other organophosphates and carbamates.

Top 25% of chemicals are ranked with a superscript of 1 to 7

b The percents calculated here is based on fewer than 25 cases and are not considered reliable.

### III. California Data - 1982 through 1995

Detailed descriptions of 11 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995) were reviewed. In all of these cases, ethoprop was used alone and was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. Ethoprop ranked 76th as a cause of systemic poisoning in California. One individual was hospitalized between 1982 and 1994. Table 2 presents the types of illnesses reported by year. Table 3 gives the total number of workers that took time off work as a result of their illness and how many were hospitalized and for how long.

Table 2: Cases Due to Ethoprop Exposure in California Reported by Type of Illness and Year, 1982-1995

	Illness Type					
Year	Systemica	Eye	Skin	Resp.	Combb	Total
1982	-	-	_	-	-	-
1983	ı	-	_	ı	_	-
1984	_	-	-	_	_	-
1985	_	-	-	_	_	_
1986	_	-	_	-	_	-
1987	_	-	-	_	_	-
1988	_	-	-	_	_	-
1989	8	1	_	2	_	11
1990	_	-	_	-	-	-
1991	_	-	_	-	-	-
1992	_	-	_	-	-	-
1993	_	-	_	-	_	-
1994	_	-	_	-	_	-
1995	-	-	-	-	_	-
Total	8	1	_	2	_	11

Table 3: Number of Persons Disabled (taking time off work) or Hospitalized for Indicated Number of Days After Ethoprop Exposure in California, 1982-1995.

	Number of Persons Disabled	Number of Persons Hospitalized
One day	-	-
Two days	1	-
3-5 days	1	1
6-10 days	1	1
more than 10 days	-	-
Unknown	-	-

A total of 8 persons had systemic illnesses or 72.7% of 11 persons. A variety of worker activities were associated with exposure to Ethoprop as illustrated in Table 4 below.

Table 4: Illnesses by Activity Categories for Ethoprop Exposure in California, 1982-1995

	Illness Category					
Activity Category <sup>a</sup>	Systemic <sup>b</sup>	Eye	Skin	Resp.	Comb <sup>c</sup>	Total
Applgrou	1	-	-	-	-	1
Driftnon	7	1	_	2	-	10
Total	8	1	_	2	-	11

<sup>&</sup>lt;sup>a</sup> Category includes cases where skin, eye, or respiratory effects were also reported

b Category includes combined irritative effects to eye, skin, and respiratory system

- <sup>a</sup> Applgrou= ground applicator; Driftnon= non-occupational exposure to drift
- b Category includes cases where skin, eye, or respiratory effects were also reported
- <sup>c</sup> Category includes combined irritative effects to eye, skin, and respiratory system

According to the above activity categories, driftnon (nonoccupational exposure to drift) was associated with the majority of the exposures. These illnesses included symptoms of shortness of breath, asthma, headaches, nausea, diarrhea, and burning eyes. A detailed investigation of the drift incident was performed by the California Department of Health Services and published in the Archives of Environmental Health by Ricard G. Ames, Ph.D., M.P.H. and James W. Stratton, M.D., M.P.H. (Acute Health Effects form Community Exposure to N-Propyl Mercaptan from an Ethoprop-Treated Potato Field in Siskiyou County, California, Volume 46, pages 213-Ethoprop had been applied at a rate of 12 pounds per acre (active ingredient) by air blasting onto the soil, tilling it in, and then irrigating the field. A questionnaire was distributed to over 900 households in the community within half a mile of the potato field where the drift/odor episode occurred and over 400 questionnaires were returned. Proximity to the potato field and perception of strong odor were used to estimate exposure to npropyl mercaptan. Direct community contact with ethoprop was not probable because it was incorporated into the soil. Data analysis using logistic regression adjusted for age, sex and smoking status found that health effects were more likely among those smelling the The most common effects associated with the odor were headache, diarrhea, runny nose, sore throat, burning/itching eyes, fever, and hay fever or asthma attacks. They concluded that the effects reported were due to the strong odor of n-propyl mercaptan, contaminant and degradation product of ethoprop. recommended that human exposures to n-propyl mercaptan be minimized to the extent practical "through pesticide use restrictions or modifications of agricultural practices."

#### IV. NPTN

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, ethoprop was ranked 182nd with 13 incidents in humans reported and 3 incidents in animals (mostly pets).

#### VI. Conclusions

Relatively few incidents of illnesses have been reported due to ethoprop. The careful investigation by the California Department of Health Services found that bystanders downwind from an ethoprop application experienced significant symptoms which were related to their perception of the strength of the odor of the mercaptan contaminant. A similar problem has been seen with DEF, another organophosphate that has a strong odor due to a mercaptan contaminant (butyl mercaptan which has a stronger, more offensive odor). Poison Center data suggest that exposures are more likely to require hospitalization than other cholinesterase inhibitors.

#### VII. Recommendations

Ethoprop does show a profile suggesting greater than average toxicity for a cholinesterase inhibitor. Application methods that prevent odor drifting to residential areas should be considered. A buffer zone of one-half mile from residential areas has been recommended for DEF which has butyl mercaptan as a contaminant. The contaminant for ethoprop has a less offensive odor but still strong enough to result in a large number of complaints from community members living near an application. A similar buffer zone should be considered for ethoprop. Alternatively, reducing the content of the contaminant n-propyl mercaptan, if practical, would be expected to reduce the complaints related to the strong odor.

cc: Correspondence
Ethoprop file (chemical no. 041101)
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